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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/856,374	05/21/2001	Ryuichi Morishita	Q64360	8301

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EXAMINER

LI, QIAN J

ART UNIT	PAPER NUMBER
1632	7

DATE MAILED: 04/11/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	09/856,374	MORISHITA ET AL.
Examiner	Art Unit	
Q. Janice Li	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 28 January 2003.

2a) This action is **FINAL**. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-9, 13-17, 19 and 20 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 1-9, 13-17, 19 and 20 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on 21 May 2001 is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some * c) None of:

1. Certified copies of the priority documents have been received.

2. Certified copies of the priority documents have been received in Application No. _____.

3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) Notice of References Cited (PTO-892)

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.

4) Interview Summary (PTO-413) Paper No(s). _____.

5) Notice of Informal Patent Application (PTO-152)

6) Other: _____.

DETAILED ACTION

The amendment filed on January 28, 2003 has been entered as Paper No 7. The Examiner assigned to examine your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to examiner Q. Janice Li, at Group Art Unit 1632.

Currently, claims 1-9, 13-17, 19, and 20 are pending and under examination, claims 1, 3-5, 7-9, 13-17 have been amended, and claims 10-12, 18, and 21-25 have been canceled.

Unless otherwise indicated, previous rejections that have been rendered moot in view of the amendment to pending claims will not be reiterated. The arguments in paper #7 would be addressed to the extent that they apply to current rejection.

Claim Objections

Claims 19 and 20 are objected to because they depend from a canceled claim (18). Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 13-17, 19, and 20 are newly rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treating or preventing cerebrovascular disorders comprising introducing an HGF gene and/or a VEGF gene into the subarachnoid space of a subject by direct injection, does not reasonably provide enablement for treating or preventing cerebrovascular disorders comprising introducing an HGF gene and/or a VEGF gene into the subarachnoid space of a subject by *any* route of administration. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The factors to be considered when determining whether the disclosure satisfies the enablement requirements and whether undue experimentation would be required to make and use the claimed invention are summarized in *In re Wands*, (858 F2d 731, 737, 8 USPQ 2d 1400, 1404, (Fed Cir.1988)). These factors include but are not limited to the nature of the invention, the state of the prior art, the relative skill of those in the art, the predictability of the art, the breadth of the claims, and amount of direction provided.

The claims read on a therapeutic method for treating or preventing cerebrovascular disorders, which method requires introducing sufficient amount of the nucleic acids encoding the therapeutic genes into the subarachnoid space. Given the broadest reasonable interpretation, the claims encompass using any route of delivery of nucleic acids into the subarachnoid space, such as intradermal, intravascular, intravenous, intramuscular, and intravenous injection. However, the only route of

administration taught by the specification is local injection into the brain tissue such as cisterna (fig. 1). It is well known in the art, that it is difficult to efficiently deliver therapeutic agents to brain tissue because of the presence of the brain-blood barrier. The specification is silent with respect to other routes of delivery and how to overcome the art known hurdles to deliver sufficient amount of therapeutic nucleic acids and proteins through the brain-blood barrier.

Therefore, in view of the limited guidance, the knowledge of the skilled in the art and the breadth of the claims, one skill in the art could not practice the invention without undue experimentation as it is broadly claimed.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 13-17, 19, and 20 are newly rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 13-17 are incomplete. The claims provide a method for treating cerebrovascular disorders, however, they do not recite any positive step which clearly relates back to the preamble, it is unclear how administration of a gene relates to the treatment of cerebrovascular disorders, and whether the goal of the method has been resolved.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

(f) he did not himself invent the subject matter sought to be patented.

Claims 1-9 are newly rejected under 35 U.S.C. 102(e) as being anticipated by *Mann et al* (US Patent No. 6,199,544).

Claims 1-9 are drawn to a composition comprising, as an active ingredient, a hepatocyte growth factor (HGF) gene and/or a VEGF gene in the form HVJ-liposome. The specification defines, “HGF/VEGF gene” means a gene that can express HGF/VEGF protein” (page 16, line 7). Claims read on a composition comprises a nucleic acid encoding a VEGF, or a HGF.

Mann et al teach a composition comprising a nucleic acid encoding the VEGF or HGF in the form of HVJ-liposomes (column 4, lines 50-57), wherein the composition is used for treatment of cerebrovascular ischemia, which ischemia is the consequence of cerebrovascular disorder, such as stroke, and which causes neuronal death.

Accordingly, *Mann et al* anticipate instant claims.

Please note that in this and the following rejections, intended use limitations for the product claims bear little weight on the determination of novelty of the invention. The

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claim limitation, "a promoting agent", or "for reducing blood flow" or "to be used in combination with HGF protein" has not given patentable weight in this and following rejections because the intended use does little toward defining structure of the claimed composition. Rather, polynucleotide sequences are relied upon for structural determination. Products of identical chemical composition cannot have mutually exclusive properties. A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. *In re Spada*, 911 F.2d 705, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990).

Claims 1-9 are newly rejected under 35 U.S.C. 102(b) as being anticipated by *WO97/07824*.

The claims read on a composition comprises a nucleic acid encoding an HGF. *WO97/07824* teaches a composition comprising a nucleic acid encoding HGF, wherein the nucleic acid is encapsulated by a liposome, and the membrane of which may be further fused to attenuated Sendai virus particles (HVJ-liposome, example 1, section bridging pages 12-13). *WO97/07824* goes on to teach that the HGF-HVJ-liposome could be used as a medicament for the treatment or prevention of human disease (2nd paragraph, page 6). Accordingly, *WO97/07824* anticipate instant claims.

Claims 1-9 are newly rejected under 35 U.S.C. 102(e) as being anticipated by *Morishita et al* (US Patent No. 6,248,722).

Morishita et al teach a composition comprising a nucleic acid encoding HGF, wherein the nucleic acid is encapsulated by a liposome, and the membrane of which may be further fused to attenuated Sendai virus particles (HVJ-liposome, example 1).

Morishita et al go on to teach that the HGF-HVJ-liposome could be used as a medicament for the treatment or prevention of human disease (column 4, lines 17-23). Accordingly, *Morishita et al* anticipate instant claims.

Claims 1-9 are provisionally rejected under 35 U.S.C. 102(e) as being anticipated by copending Application No. 09/660,522 which has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the copending application, it would constitute prior art under 35 U.S.C. 102(e), if published under 35 U.S.C. 122(b) or patented. This provisional rejection under 35 U.S.C. 102(e) is based upon a presumption of future publication or patenting of the copending application.

The reference application qualifies as prior art under this provision because it has a different inventive entity and no showing of common ownership between the instant application and the cited application.

The cited copending application is a continuation of US patent 6,248,722, therefore the reasoning presented in the immediate preceding rejection applies to the cited copending application because the disclosure of the cited copending application and the '722 patent is the same.

This provisional rejection might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the copending application was derived from the inventor of this application and is thus not the invention "by another," or by a showing of a date of invention for the instant application prior to the effective U.S. filing date of the copending application under 37 CFR 1.131. For applications filed on or

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after November 29, 1999, this rejection might also be overcome by showing that the subject matter of the reference and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person. See MPEP § 706.02(I)(1) and §706.02(I)(2).

Claims 1-9 are newly rejected under 35 U.S.C. 102(f) because the applicant did not invent the claimed subject matter.

U.S. Patent No. 6,248,722 has a different inventive entity with the instant application; however, the cited patent anticipates the claimed subject matter. Further clarification is required with regard to the inventorship.

Claims 1-9 are provisionally rejected under 35 U.S.C. 102(f) because the applicant did not invent the claimed subject matter.

U.S. Patent Application Serial No: 09/660,522 has a different inventive entity with the instant application; however, the claimed subject matter is anticipated by the cited application. Further clarification is required with regard to the inventorship.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-9, and 13-17 are newly rejected under 35 U.S.C. 103(a) as being unpatentable over *Isner et al* (US 6,121,246 or WO 97/14307), and *Morishita et al* (US Patent No. 6,248,722), in view of *Ghodsi et al* (Hum Gene Ther 1998;9:2331-40).

Claims 1-9 read on a composition comprising a nucleic acid encoding two polypeptides, HGF and VEGF, in the form of HVJ-liposome.

Isner et al teach a composition for treating any tissue ischemia including "cerebrovascular ischemia" (abstract), which is well known to the skilled artisan that it would occur as the consequence of cerebrovascular obstruction or stroke and it would cause neuronal cell death; *Isner et al* go on to teach that the composition comprises a nucleic acid encoding an angiogenic protein selected from the group consisting of FGF, HGF, EGF, VEGF, and optionally further comprises a micro-delivery vehicle such as cationic liposomes and viral vectors (column 3, lines 4-25). They teach that in certain situations, it may be desirable to use nucleic acids encoding additional different proteins such as the combination of FGF, HGF, EGF, VEGF, in order to optimized the

therapeutic outcome (column 6, lines 4-8). *Isner et al* do not particularly teach an HVJ-liposome carrier.

Morishita et al teach delivering a nucleic acid encoding HGF, particularly since HGF has a short half-life *in vivo*, it is preferred to administering HGF locally at the site of injury, and in the form of liposome (column 1, lines 46-67). A preferred embodiment is HGF in the form of HVJ-liposome, which could be produced and secreted in endothelial cells at a high level (Example 1).

Claims 13-17 are drawn to a method comprising introducing an HGF and/or VEGF gene in the form of HVJ-liposome into the subarachnoid space in humans, and the specification teaches this is done by injection into the cisterna (page 10, line 4).

Isner et al teach treating ischemia by local injection to more than one site in the ischemic tissue, in the case of cerebrovascular ischemia, the brain tissue (paragraph bridging columns 2 & 3). *Morishita et al* teach that HGF has diverse pharmacological activities and could be used to treat many different diseases, such as nervous disorders (column 1, lines 12-26) and arterial diseases (claim 3), which encompass cerebrovascular disorders. *Morishita et al* also teach that *in vivo* administration could be achieved via many routes such as directly into the brain tissue to selectively obtain a therapeutic effect (column 6, lines 5-14). *Isner et al* or *Morishita et al* do not particularly teach injection into subarachnoid space.

Ghodsi et al teach introducing an adenoviral vector to central nervous system via cisterna magna injection, and the vector could be seen throughout many parts of the brain tissue.

Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the methods taught by *Isner et al* and *Morishita et al* by simply administering the HGF and/or VEGF gene in the form of HVJ-liposome into the subarachnoid space with a reasonable expectation of success. The ordinary skilled artisan would have been motivated to modify the method because the HVJ-liposome carrier and the cisterna injection have been proven effective to reach multiple compartments of the brain and obtain high levels of HGF expression in vascular endothelial cells. Thus, the claimed invention as a whole was *prima facie* obvious in the absence of evidence to the contrary.

In paper No 6, applicants argue that neither *Isner* nor *Morishita* teach or even suggest that the HGF or VEGF gene in the form of HVJ-liposome is effective for the treatment of cerebrovascular disorders. In response, as indicated above, *Isner et al* teach treating cerebrovascular ischemia, which is a cerebrovascular disorder, with nucleic acids expressing HGF and VEGF and delivered with a microvehicle such as liposomes, and *Morishita et al* teach treating an arterial disorder including brain tissue arterial disorder (cerebrovascular disorder) using any type of nucleic acid vehicle (claims 1 and 2) including and particularly HVJ-liposome (claim 4). Therefore, the combined teachings of *Isner et al* and *Morishita et al* as a whole suggest that the HGF and/or VEGF gene in the form of HVJ-liposome is effective for the treatment of cerebrovascular disorders. Further, the method step taught by *Isner et al*, *Morishita et al* and *Ghodsi et al* is the same as the presently claimed method, thus, it would achieve the objectives. Please note that intended use limitations bear little weight on the

determination of novelty of the invention. In this case, for example, the limitation "for reducing blood flow" in claim 14, or "for suppressing apoptosis of nerve cells" does not carry patentable weight in the determination of anticipation for the claimed methods. This is because a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). Moreover, it is a general rule that merely discovering and claiming a new benefit to an old process cannot render the process again patentable. *In re Woodruff* 919 F. 2d 1575, 1577-78, 16 USPQ2d 1934, 1936-37 (Fed. Cir. 1990); *In re Swinehart*, 439 F. 2d 210, 213, 169 USPQ 226, 229 (CCPA 1971); and *Ex Parte Novitski*, 26 USPQ2d 1389, 1391 (Bd. Pat. App. & Int. 1993).

Claims 1-9, 13-17, 19, and 20 are newly rejected under 35 U.S.C. 103(a) as being unpatentable over *Isner et al* (US 6,121,246 or WO 97/14307), *Morishita et al* (US Patent No. 6,248,722), and *Ghodsi et al* (Hum Gene Ther 1998;9:2331-40) as applied to claims 1-9 and 13-17 above, and further in view of *Mann et al* (US Patent No. 6,199,544).

Claims 19 and 20 are drawn to a therapeutic regimen that combines the use of HGF and/or VEGF protein with that of nucleic acids expressing HGF and/or VEGF. The

combined teaching of *Isner et al*, *Morishita et al* and *Ghodsi et al* fails to suggest such a course of therapy.

However, *Mann et al* clearly teach combining multiple means of therapy to treat ischemic condition. *Mann et al* teach enhancing vascularization in an ischemic tissue by inducing thermal injury combined with delivery of a pro-angiogenic factor such as VEGF and HGF in the form of proteins or nucleic acids (column 1, lines 26-45), preferably the nucleic acid is in the form of HVJ-liposome (e.g. column 4, line 50). They go on to teach that the advantage of providing for possibly more global factor/DNA delivery combined with local TMR, i.e. the combined therapy allows for a disparity in timing between TMR and drug or nucleic acid delivery (column 3, lines 23-28), that the interaction between the two treatments results in greater revascularization than observed with either treatment alone (column 3, lines 50-52), and that a gene encoding for a proangiogenic agent to produce sustained local protein production could obviate the need for repeated administration of a protein (column 7, lines 52-56).

In paper No 6, applicants argue that *Mann et al* do not teach administering a protein along with the DNA. While true, *Mann et al* teach the nucleic acids or proteins as alternative for combining with TMR, not combining between the nucleic acids and proteins, it is clearly known to the skilled artisan that both nucleic acids and proteins of HGF and/or VEGF are effective in treating the ischemic tissue, that a protein would have temporary effect while the nucleic acids have long lasting effects.

Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the methods taught by *Isner et al* and *Morishita*

et al and *Ghodsi et al* by simply administering the HGF and/or VEGF gene together with the HGF and/or VEGF protein with a reasonable expectation of success. The ordinary skilled artisan would have been motivated to modify the method because the pharmaceutical consequence of a protein affect immediately while the expression of proteins by the nucleic acids have long lasting effects. Thus, the claimed invention as a whole was *prima facie* obvious in the absence of evidence to the contrary.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-9 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-11 of U.S. Patent Application Serial No. 09/857,719.

Claims 1-9 are directed to an invention not patentably distinct from claims 1-11 of copending application 09/857,719. Specifically, although the conflicting claims are not identical, they are not patentably distinct from each other because the present

application and claims 1-11 of the cited application are each drawn to an agent comprising the HGF gene as an active ingredient in the form of HVJ-liposome.

The claims of the present application and the cited patent differ one from the other in that the instant claims may further comprises an additional protein VEGF, however, they also encompass an HGF gene alone in the form of HVJ-liposome. The claims of the present and copending applications further differ one from the other in that the intended uses of the composition are directed to treating different types of diseases. However, the novelty of the composition is determined by the chemical structure of the HGF gene and nucleic acids that expressing the HGF, not the intended use.

Accordingly, the inventions as claimed are co-extensive.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Q. Janice Li whose telephone number is 703-308-7942. The examiner can normally be reached on 8:30 am - 5 p.m., Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah J. Reynolds can be reached on 703-305-4051. The fax numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of formal matters can be directed to the patent analyst, Dianiece Jacobs, whose telephone number is (703) 305-3388.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235. The faxing of such papers must conform to the notice published in the Official Gazette 1096 OG 30 (November 15, 1989).



Q. Janice Li
Patent Examiner
Art Unit 1632


April 7, 2003